

## Package Insert for Cystatin C Calibrator Kit on Beckman Coulter® AU, IMMAGE, Synchron and UniCel Systems

REF A52763

### Intended Use

The Gentian Cystatin C Immunoassay is an *in vitro* diagnostic test for quantitative determination of cystatin C in human serum and plasma. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

### Gentian Cystatin C Calibrator Kit Intended use

The Gentian Cystatin C Calibrator Kit is intended to be used to establish a calibration curve for measuring cystatin C concentration in human serum or plasma with the Gentian Cystatin C Immunoassay.

### Reagent Information

#### Composition

The Gentian Cystatin C Calibrator Kit is made from a delipidated human serum pool spiked with human cystatin C. Antibiotics are used as preservative. The calibrators are ready to use.

#### Calibrator Value Assignment

The calibrator values, given in the enclosed analytical value sheet, is assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. The calibrator comprises of human cystatin C.

#### Calibrator Standardisation

Gentian Cystatin C Calibrator Kit is standardised against the international calibrator standard ERM-DA471/IFCC.

#### Items provided:

Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL	REF A52763
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#### Additional items required for use on DxC system:

Gentian Cystatin C Reagent Kit	REF A52761
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Gentian Cystatin C Control Kit, Low & High, vials of 1 mL	REF A52765
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User-Defined Reagent Cartridge (pkg. of 12)	REF 442835
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#### Additional items required for use on AU system:

Gentian Cystatin C Reagent Kit for AU systems	REF B08179
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Gentian Cystatin C Control Kit, Low & High, vials of 1 mL	REF A52765
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#### Additional items required for use on IMMAGE system:

Gentian Cystatin C Reagent Kit	REF A52761
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Gentian Cystatin C Control Kit, Low & High, vials of 1 mL	REF A52765
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User-Defined Reagent Cartridge (pkg. of 10)	REF 447250
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Evaporation Caps (pkg. of 20)	REF447170
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### Storage

Shelf life of unopened reagents at 2 - 8°C: See expiry date on the label.  
 Stability after opening: 6 months at 2 - 8°C.

### Establishing the Calibration Curve

Use the standards 1 to 6 to establish a 6-point standard curve as defined in the Beckman Coulter AU, IMMAGE, Synchron or UniCel system instrument manuals. This should be performed once every 4 weeks. Calibrator values are lot dependent and a new calibration must be performed whenever a new calibration lot is used. The calibrator's assigned values are given on the analytical value sheet provided with the calibrator.

### QC Controls

The low and high controls must be assayed each day before any sample is assayed in order to validate the calibration curve. If the control values are not valid, repeat the control measurements. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact Beckman Coulter® for support.

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### Warnings and Precautions

1. The Gentian Cystatin C Calibrator Kit is for *in vitro* use only, and must be handled by qualified personnel.
2. The Gentian Cystatin C Calibrator Kit contains antibiotics and must be handled with due cautions.
3. Serum used in the manufacturing of the Gentian Cystatin C Calibrator Kit is tested for hepatitis HBsAG, anti-HCV, anti-HIV1 and anti-HIV2 and found to be negative. Nevertheless, the materials contain substances of human origin and must be handled with due care. Disposal of any discarded materials should be in accordance to local requirements.

### Additional Information

For more detailed information on AU, IMMAGE, Synchron and UniCel Systems, refer to the appropriate system manual. As Beckman Coulter® does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter® cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

### Shipping Damage

Please notify your distributor if this product is received damaged. For technical assistance please contact your local Beckman Coulter® representative.

For other languages visit:

<https://www.gentian.com/clinical-diagnostic-products/beckman-coulter-customers-cystatin-c>

### Symbols Key

- Lot number
- Temperature limit
- Use by date
- Consult instructions for use
- Manufacturer
- Catalogue number
- In vitro diagnostic medical device
- Caution
- Biological risks

**Gentian AS**

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### Bibliography

[1] ISO 17511; In Vitro Diagnostic Medical Devices - Measurement of Quantities in Biological Samples - Metrological Traceability of Values Assigned to Calibrators and Control Materials. First edition 2003-08-15